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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,122	10/13/2000	Alessandra Boe	P/717-181(CONT)	6984
1444	7590	08/09/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C.			MURPHY, JOSEPH F	
624 NINTH STREET, NW				
SUITE 300			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20001-5303			1646	

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/687,122

**Applicant(s)**

BOE ET AL.

**Examiner**

Joseph F Murphy

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-32 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 and 25-29 is/are rejected.
- 7) ☒ Claim(s) 30-31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

DETAILED ACTION

*Formal Matters*

Claim 21-32 are pending. Claims 22-24, 32 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 21, 25-31 are under consideration.

*Response to Amendment and Arguments*

Applicant's arguments filed 6/2/2004 have been fully considered but they are not persuasive, for the reasons set forth below.

*Claim Rejections - 35 USC § 112 first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 25-29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating septic shock by administration of a TNF receptor, or TBP-1 in combination with DHEA, does not reasonably provide enablement for a method of treating autoimmune and inflammatory diseases by administration of a TNF receptor, or TBP-1 in combination with DHEA, for reasons of record set forth in Paper No. 13, 5/5/2003 and 11/25/2003. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The rejection of record set forth that claim 21 is directed to a method of treatment of autoimmune and inflammatory disease in a patient by administration of DHEA in combination with a TNF receptor, while claims 25-29 are directed to methods of treatment of autoimmune

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and inflammatory diseases in a patient by administration of DHEA in combination with TBP-1.

Thus, the claim encompass the treatment of any and all inflammatory and autoimmune diseases by administration of a TNF receptor, including TBP-1, in combination with DHEA.

Applicant has amended the claims to change claim 21 into the Jepson format with the known process in the preamble and the improvement in the body of the claim. Applicant argues that the claim is directed only to the treatment of autoimmune and now inflammatory diseases against which a TNF receptor is effective, and that the improvement is administering the TNF receptor in combination with DHEA. Applicant further argues that the present application does not purport to disclose any new discoveries as to what diseases or conditions may be treated by TNF-R. However, while the preamble of a claim in the Jepson format serves as an admission that it is prior art to the instant application (see *In re Fout* 675 F.2d 297 and MPEP 2129), it does not serve as a limitation on the claim whereby the claim is limited to only what is known in the prior art. Here, the claims encompass methods treatment of any and all inflammatory and autoimmune diseases by administration of a TNF receptor, including TBP-1, in combination with DHEA, While the Specification demonstrates the effectiveness of the claimed treatment in a septic shock model, and the art teaches the effectiveness of TNF receptor alone in RA, SLE and the NOD mouse model of diabetes, this is not demonstrative of any and all autoimmune and inflammatory conditions, and does not enable one of skill in the art to treat any and all autoimmune and inflammatory conditions using the claimed method. The previous Office Action cited art that teaches that TNF is not involved in all autoimmune and inflammatory disorders. The cited art recognizes that there are distinct disease processes involved in septic shock, other types of inflammation, and autoimmune diseases. Ulevich et al. teaches that the mechanism of septic

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shock is the binding of LPS by LPS Binding Protein (LBP) and the binding of LPS-LBP complex by CD14 (Ulevitch et al. at 438). The mechanism underlying the development of autoimmune and autoimmune inflammatory diseases is set forth in The Merck Manual which teaches that autoimmune disorders are the result of the immune system producing autoantibodies to an endogenous antigen with consequent injury to tissues. Mechanisms for the development of an immune response to autoantigens include, *inter alia*, the release of hidden or sequestered antigens into the circulation, the alteration of self-antigens into an immunogenic form, cross-reaction of a foreign antigen with a self-antigen (Merck Manual, page 1061). In addition, the previous Office action also cited art showing that while the LPS model can be used to test the efficacy of therapeutic regimens for the treatment of septic shock, separate models are required to test the efficacy of the claimed treatments for efficacy in other inflammatory, or autoimmune diseases (U.S. patent No. 6,054,487, column 20, lines 20-35). No nexus is provided between the treatment of RA, SLE, the NOD mouse model of diabetes, or septic shock and any and all other inflammatory and autoimmune diseases. Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claims encompass methods for which the skilled artisan would need to carry out experimentation to determine the effectiveness of the claimed treatment method in any and all other autoimmune and inflammatory conditions. Since the nexus between the treatment of RA, SLE, the NOD mouse model of diabetes or septic shock, and the treatment of any and all autoimmune and inflammatory diseases is not set forth in the Specification, or recognized in the art, this experimentation would be undue since no teachings are provided that would allow one of skill in the art to predict that the claimed method would be efficacious in treating any and all other autoimmune and inflammatory diseases.

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*Conclusion*

Claims 30-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 21, 25-29 are rejected.

*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.


The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
August 3, 2004



JOSEPH MURPHY  
PATENT EXAMINER